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Policy Brief

Patents and emergencies: Lessons (not) learnt from the COVID-19 pandemic

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Executive summary

After the identification of the COVID-19 virus, the fast development of vaccines reveals the availability of an extremely rich body of consolidated knowledge waiting for its therapeutic exploitation. Such knowledge largely originates in public or non-profit institutions and explored either there or in spin-offs. However, notwithstanding the large amount of public money provided by the U.S.A. and the E.U. to Big Pharma for the development of COVID vaccines, even many developed economies had been rationed in the vaccine supply, while Global South countries still struggle to fully vaccinate their population. The current situation has an impact on the society and economy of both Global South and developed countries and it favours the possible emergence of new variants of the virus, such as the Delta and Omicron. Yet, pharmaceutical companies such as BioNTech, Moderna and Pfizer are reaping skyrocketing profits. The pandemic crisis has shown the dramatic consequences of the neglect by the State of the universal public good character of health, and the corresponding extension of the market domain. As the flexibilities offered by the current international IP regime under the WTO TRIPs agreement – including mandatory licenses – have shown not be enough to respond to the challenges posed by the COVID-19 pandemic, India, South Africa and more than 100 countries have asked a temporary TRIPs waiver from obligations on patents, trade secrets, industrial design and copyright related to medicines, vaccines, diagnostics and other related COVID-19 technologies and materials. However, the European Union has long and fiercely opposed such a temporary TRIPS waiver, pushing for the adoption of a compromise text that drastically reduced the scope of the original proposal and frustrated most of its potential.

In this policy brief we comment on the original TRIPs waiver proposal and illustrate why its broader approach would have constituted the best response to effectively transfer knowledge to Global South countries, thus fixing the worldwide structural underproduction and distributions not only of vaccines but also of other drugs and medical devices that are fundamental to reduce the COVID-related mortality rate, yet without hampering the innovation rate in the pharmaceutical industry. Against this background, we critically assess the compromise text that was adopted by the TRIPs Ministerial Council on 17 June 2022, highlighting its most evident shortcomings. On this basis, we argue that, beyond this weak emergency response, a structural reform of the TRIP treaty is needed to i) broaden the fields of technologies exempted from patentability; ii) increase IP flexibilities and derogations; iii) exclude commercial sanctions for violations backed from external motions of international organizations. Moreover, the E.U. must reform the Unitary Patent Package to harmonize the treatment of publicly funded inventions and the regulation of compulsory licenses, as well as to provide a uniform system of exceptions across the Union, introducing a system of EU-wide compulsory licenses. Such reforms are needed to terminate the "regulatory capture" in the relationship between the E.U. and private pharmaceutical companies and reconsider health as a global public good. This, together with innovation and industrial policies, would accelerate innovation in the pharmaceutical industry, boosting the development of new drugs and vaccines, while reducing the financial costs for EU-country budgets, severely hit by the COVID crises.

FACTS AND FINDINGS

- The fast development of COVID-19 vaccines rest on the availability of an extremely rich body of consolidated knowledge mostly originated in public or non-profit institutions.
- Notwithstanding the large amount of public money provided by the U.S.A. and the E.U. to Big Pharma for the development of COVID-19 vaccine, there is a structural under-supply of vaccine jabs, life-saving drug and medical devices while private companies' profits skyrocket.
- Pharmaceutical companies have reaped extraordinary profits from vaccine production.

PROBLEMS AND CHALLENGES

- The flexibilities offered by the WTO TRIPs Agreement - including compulsory licenses - are not enough to respond to the challenges posed by systemic, worldwide emergencies such as the COVID-19 pandemic
- There are signs of "regulatory capture" in the public-private relationship undergoing the development and distribution of COVID vaccines.
- The current approved TRIPs waiver represents a step forward but fails to respond to the most fundamental challenges raised by the pandemic, and it features several limitations that frustrate its potential.

REFORM PROPOSALS

- A broader ad-hoc TRIP waiver from obligations on patents, trade secrets, industrial design and copyright related to medicines, vaccines, diagnostics and other related COVID-19 technologies and materials should be still considered.
- Structural reform of the TRIP treaty should be introduced to broaden the fields of technologies exempted from patentability, increase IP flexibilities and derogations, exclude commercial sanctions for violations backed from external motions of international organizations.
- EU must reform the Unitary Patent Package to harmonize the treatment of publicly funded inventions, harmonize the regulation of compulsory licenses and provide a uniform system of exceptions across the Union, introducing a system of EU-wide compulsory licenses.
- Innovation and industrial policies to boost innovation in the pharmaceutical sector are complementary to a reform of the IPR regime.

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Almost more than two years after the unexpected outburst of the COVID-19 pandemic, and with the number of vaccine shots available in the Global North now being capable of meeting the demand, the debate on patents and access to medicine has again lost traction. However, the emergence of the Omicron variant and the waning of 2- and 3-dose vaccine protection is a strong reminder of the importance of vaccinating the whole world and of building extra vaccine production capacity. In fact, this solve-and-forget mechanism mirrors the path followed in the early 2000s *vis-à-vis* the HIV pandemic. Back then, after the WTO issued the *Doha Declaration on TRIPs and Public Health*, and compulsory licenses and NGOs' campaigns pushed down the price of retroviral treatments for HIV in developing and least developed countries (Matthews-Correa 2011), no follow-up evaluation was performed on the suitability of the new international IP regime to strike an effective and evidence-based balance between incentive and access needs.

While developed countries have administered boosters to contain the fourth pandemic wave, in most African countries less than 30% of the population has received at least one dose. Parallel to this, the proposal of a TRIPs waiver advanced by India and South Africa to address the burning needs for vaccines, drugs and medical devices that are fundamental to reduce the COVID-related mortality rate in the Global South has long run aground due to the disagreement expressed by the EU. For months and months, the drying-out policy debate has revolved around the rhetoric of a seemingly impossible-to-break equation between patent protection and vaccine development. This has led to the approval of a compromise text of TRIPs waiver on 17 June 2022,[1] which has substantially scaled down the scope of the original proposal and largely frustrated the potential the instrument could have had in tackling the challenges the pandemic has raised and the divide it has broadened between the Global North and the Global South.

The aim of this policy brief is to critically assess the response offered by the TRIPs Council, revive the debate, elaborate on the lessons not learnt from the COVID-19 emergency, and propose policy actions along and beyond the TRIPs waiver to transform the WTO IP system in a fairer and emergency-proof regime. Such changes together with industrial and innovation policies should boost innovation in the pharmaceutical sector and increase the production of life-saving vaccines and drugs.

[1] WTO Ministerial Conference, Twelfth Session, Geneva, 12-15 June 2022, Draft Ministerial Decision on the TRIPs Agreement, WT/MIN(22)/W/15/Rev.1, 17 June 2022. The draft text is available at https://docs.wto.org/dol2fe/Pages/SS/directdoc.aspx?filename=q:/WT/MIN22/W15R1.pdf&Open=True (last accessed 18 June 2022).

1. What we have learnt from the COVID-19 pandemic: facts, policy responses and take-aways

a. Facts

There are a number of key medical, economic and policy findings by the pandemic, which is worth recalling and elaborating upon.

(i) In less than one year after the identification of the COVID-19 virus, many vaccines have become available, and others have been put in the pipeline. Vaccine usually takes years of research to be developed and tested. The fast response to the COVID threat reveals the availability of an extremely rich body of consolidated knowledge waiting for its therapeutic exploitation. In particular, Pfizer-BioNTech and Moderna vaccines were obtained by imaginative re-applications of mRNA studies originally concerning cancers.

(ii) Equally striking is that such knowledge is largely originated in public or non-profit institutions (Oxford University, UK; MIT and Harvard, US; Gamaleya Institute, Russia; University of Mainz, Germany; Finlay Institute, Cuba; etc.) and explored either there or in spin-offs thereof (e.g., BioNTech, Moderna). Indeed, basic research is almost entirely supported and often also performed by the public sector in both Europe and the USA.[2] Symmetrically, there is longer-term evidence that the private sector decreased its investment in basic research (Arora et al. 2018).[3]

(iii) Notwithstanding the large amount of public money provided by the U.S.A. ($ 18 billions) and the E.U. (EUR 8 billion) to Big Pharma for the development of COVID vaccine,[4] even developed economy had been rationed in the vaccine supply (with the exception of the USA, UK and Israel), let alone the disastrous conditions of Global South countries, which receives less than 1% of total production.

(iv) Related to the previous point, the COVID pandemic is exacerbating the existing inequalities between developed and middle- and low-income countries with huge social and economic costs also for the former ones. Indeed, a recent study (Çakmaklı et al., 2021) shows that in 2021, 49% of the pandemic economic costs will be borne by developed countries even if they vaccinate the whole population. The estimates are conservative as they do not consider the possible emergence of new variants of the virus, such as the Delta and Omicron.

(v) The pandemic crisis has dramatically highlighted the damages of the neglect, or, in some countries, the retreat by the State from a universal public good – health, and the corresponding extension

[2] In the USA, all 210 New Chemical Entities approved by the FDA in the period 2010-2016 got funding, to different degrees, from the National Institutes of Health (NIH), see Cleary et al., (2018). Incidentally, notice that also some patents crucial for mRNA techniques have a public origin and are detained by public institutions (e.g. the National Institutes of Health).

[3] Among the New Molecular Entities approved by the FDA since the year 2000, less than 6 % concerned antibiotics or anti-viral drugs (Walker, 2020).

[4] Pfizer made net profits of nearly $22bn in 2021, up from $9.1bn in 2020; Moderna's net income amount to $12.2bn in 2021 against a net loss of $747m in 2020; BioNTech profits jump to $11.5bn in 2021, up from $17m in 2020.

of the market domain (more in Nelson, 2005), vividly captured by the scenes of serious patients unable to reach hospitals not only in Global South countries but also in developed ones.

b. Policy debates and responses

Two common leitmotifs have animated op-eds and general policy discourses. One is that the WTO TRIPs agreement does not offer adequate leeway and instruments to tackle the shortage of vaccines, live-saving drugs and medical devices particularly in developing countries. The second is that the "political economy" of the public-private relationship revealed by national policy responses has gone well beyond the "regulatory capture", to the point of reversing the relationship between the State and the private actors, enshrined even in the most pro-market constitutions. Both statements are at least partially incorrect: in fact, the TRIPs Agreement gives some room to tackle the emergency, while there is – for instance – a remarkable difference in the degree of regulatory capture showed by similarly powerful and developed economies, such as the US and the EU. A concise fact check is enough to highlight such flaws in the public debate, and it also leads to additional interesting findings.

(i) As to the flexibilities offered by the TRIPs Agreement, it is well known that Article 31 allows WTO Member States to introduce compulsory licenses also for the case of national emergencies or other cases of extreme urgency, which after the *Doha Declaration on TRIPs and the Public Health* is left for the discretion of national governments to determine. This implies that the provision may accommodate the needs of developed and developing countries alike.

What the policy debate tends NOT to emphasize is the scarce usefulness of such a tool for countries having weak or no manufacturing capabilities. The problem has been addressed by the TRIPs Council, which introduced Article 31*bis* to allow the issuance of compulsory license by a country with the aim of exporting generic pharmaceutical products to an eligible importing Member State qualified as a least-developed country. Despite all good intentions, the great complexity of the process and of the requirements imposed on exporting and importing countries have drastically reduced Article 31*bis* potentials, as testified by the very few cross-compulsory licenses issued on this basis (Vincent, 2021).

There are also other largely neglected aspects that make compulsory licenses under Articles 31 and 31bis TRIPs not the best tool to address key challenges arising in a global pandemic. First, their use may be hindered by pressures from trading partners and pharmaceutical companies, and by the fear of commercial retaliations or legal disputes. Second, they need a case-by-case, product-by-product and country-by-country approach, which makes it impossible to coordinate efforts in different jurisdictions. Third, they remove existing patent barriers on single products, but cannot do much when an invention and the knowledge necessary for its implementation are subsequently protected by new/additional IP rights, or when parts of the technology necessary for production and supply are kept secret. Fourth,

compulsory licenses are to be used predominantly for the domestic market. Article 31bis TRIPs offers the possibility to issue licenses directed to produce generics for countries having no manufacturing capabilities, but its requirements and processes are so complex and articulated that the instrument have been used no more than two times since its entry into force in 2017 (Vincent, 2021). In fact, compulsory licenses for export have been proven impractical and logistically hard to implement also during the COVID-19 pandemic, as the Canada-Bolivia example perfectly shows (MSF, 2021).[5]

Another largely neglected aspect is that compulsory licenses are not enough to transfer to third parties all the knowledge needed to implement the protected invention. Know-how, confidential information, trade secrets, other IP rights and protected data outside the patent application may be essential to manufacture the product or used to block the production, yet there is no regulatory tool to oblige patent owners to transmit them to compulsory licensees. In addition, complex supply chains may require a large number of compulsory licenses to get access to the main components of a pharmaceutical product. As explained by the International Federation of Pharmaceutical Manufacturers and Associations (IFRMA), "The BioNTech/Pfizer vaccine contains 280 ingredients sourced from 19 countries. Moderna's AstraZeneca's and Johnson & Johnson's are similarly complex" (Cueni 2020). If the subject-matter of the license is a groundbreaking innovation featuring a complex IP structure, as it is the case for the mRNA-based vaccines, the mere issuance of a license might not be enough to allow generic production and increase accessible distribution.

(ii) As to the "regulatory capture" of developed countries, and particularly of IP exporters hosting the seats of multinational pharmaceutical countries, it is worth noting the great divergences in the approaches adopted by the European Union and the United States.

The EU decided not to exercise the political, economic and regulatory pressure it would have been able to and focused instead on signing the best possible contract with pharmaceutical companies, assuming that "the markets know better". Once the Union decided to negotiate as a single delegation with Astra Zeneca, Pfizer and Moderna for the centralized supplies of doses to be distributed to local governments, it implicitly crossed out the political possibility for Member States to enact national compulsory licensing schemes. This came as a further complication to an already flawed and fragmented regulatory framework, where compulsory licenses and other form of patent flexibilities were (and are) still not harmonized across the EU, a handful of national patent laws did not provide for compulsory licenses for

[5] In February 2021 Bolivia notified the WTO TRIPs Council of its intention of becoming an importing country under Article 31bis TRIPs. In March 2021 a Canadian vaccine producer, Biolyse, issued a press release reporting that it attempted but failed to stipulate a license with Johnson & Johnson to produce its vaccine for domestic supply and export, and that it had the capacity to start producing immediately. On this basis, Biolyse aimed at obtaining a compulsory license for export under Canada's Access to Medicines Regime (CAMR) – the national implementation of the mechanism required under Article 31bis TRIPs. In May 2021, Bolivia entered into an agreement with Biolyse for the supply of 15 million doses of vaccine. As of today, they are still waiting for the Canadian government to issue the compulsory license necessary to kick off the process.

health emergencies,[6] and the new EU Unitary Patent – not in force yet – is completely silent on the issue. In addition, no other policy measure has been implemented to intervene on the process of development, testing, manufacturing, and distribution of vaccines.

On the contrary, the United States have kept in place a thorough system of command and control with *Operation Warp Speed (*see Adler 2021 and Bown and Bollyky, 2021*)* within the framework of the Defense Production Act (DPA), the Pandemic and All-Hazards Preparedness and Advancing Innovation Act (PAHPAIA), and the Coronavirus Preparedness and Response Supplemental Appropriations Act (CPRSA). The philosophy underlying this panoply of regulatory interventions is a comprehensive mix of compulsory previsions and allocation of resources to the private sector in order to incentivize public-private partnership, enable faster approval and production of vaccines, and ensure compliance by vaccine producers (Hickey et al, 2020).

Operation Warp Speed was initially funded with $10 billion from the Coronavirus Aid, Relief and Economic Security (CARES) Act, passed in March 2020 as an interagency program, later increased to $18 billions in October 2020.[7] It used the Biomedical Advanced Research and Development Authority (BARDA) as the main financial interface. By August 2020, eight companies were selected for funding and received $11 billion to sustain and accelerate the development and production of their vaccine candidates. Additional funding was provided by the Congress with the Coronavirus Preparedness and Response Supplemental Appropriations Act (CPRSA). Both the CARES Act and the CPRSA coupled the financial contributions with two provisions related to the affordability of COVID-19 related drugs: (a) products including vaccines, therapeutics, and diagnostics devices, purchased by the federal government using CRPSA/CARES funds, "shall be purchased in accordance with Federal Acquisition Regulation guidance on fair and reasonable pricing"; (b) the Secretary of HHS may take measures to ensure that vaccines, therapeutics, and diagnostics developed from CRPSA/CARES funds will be affordable in the commercial market. These policy measures flanked already existing regulatory tools that offer a stronger bargaining position to the US government vis-à-vis commercial parties in case of national emergencies, the most relevant one being the Bayh-Dole Act of 1980, which applies to inventions conceived/produced in the context of a funding agreement with a federal agency. The Act allows the contractor to retain patent rights, but only upon granting in exchange a government-use license to the agency, while the US retains the power to grant compulsory licenses to third parties in special circumstances (march-in-rights,

[6] Such as Italy, which introduced it only in July 2021 (art.71bis CPI)

[7] Operation Warp Speed witnessed the large participation of several public and private actors, among which the Department of Health and Human Services, including the Centers for Disease Control and Prevention, Food and Drug Administration, the National Institutes of Health, and the Biomedical Advanced Research and Development Authority (BARDA); the Department of Defense; private firms; and other federal agencies, including the Department of Agriculture, the Department of Energy, and the Department of Veterans Affairs.

35 U.S.C. § 203).[8] Similar rules apply in case of public-private cooperative research and development agreement (CRADAs) that do not entail federal funding.[9]

The march-in right may be triggered every time action is necessary to remedy to the non-use of the patent or alleviate health or safety needs and requirements for public use that are not reasonably satisfied by the contractor. In fact, the provision has never been triggered by the Federal Government,[10] but the tool constitutes a powerful weapon when negotiating with patent owners. The same applies for governmental use rights (28 U.S.C. §1498), which cover all patented inventions and give to the federal government the power to use or manufacture any patented invention, either directly or by means of the issuance of a compulsory license. Evidence of the power of such a measure comes from one of its most famous uses in history. In 2001, the threat of the use of anthrax as a chemical weapon led the US to request Bayer a massive amount of the antibiotic ciprofloxacin (Cipro) to stockpile them. When Bayer resisted against raising the production level and offering Cipro at a reasonable price, the US government threatened the use of §1498, which led to an immediate acceptance of the order and a 50% decrease in Cipro's price (Kapczynski and Kesselheim 2016). Along the same lines, in December 2020 President Trump issued an executive order compelling pharmaceutical companies to give priority access to the US government or vaccines developed in the US, implementing again a command-and-control strategy which is clearly made possible by a favourable regulatory framework.

c. Three take-aways

Three points stand out clearly from such findings:

(a) There is a structural underproduction of vaccine which directly hurt especially Sub-Saharian African countries, but it indirectly affects world economies and society via supply-chain relationships, endemic uncertainty and the emergence of new strong variants as witnessed by the surge of Omicron. In order to tackle such North-South inequality and build world resiliency against the COVID-19 pandemics, both patent waivers and industrial policy for technological transfer and local manufacturing are required.

(b) The flexibilities offered by the current international IP regime under the WTO TRIPs Agreement are not enough to respond to the challenges posed by systemic, worldwide emergencies such as the COVID-19 pandemic.

[8] Despite the Act is formally limited to contractors that are non-profit organizations or small business, executive practice and regulations have applied it to all contractors, regardless of their nature and size.

[9] While IP ownership is defined by the cooperation agreement, the federal government always retains a government-use license and compulsory-licensing authority similar to Bayh-Dole march-in rights.

[10] CRS Report R44597, *March-In Rights Under the Bayh-Dole Act*, at 8. Requests moved by advocacy groups to activate it against the high pricing of certain medicines has been rejected by arguing that pricing concerns alone are not enough to exercise the march-in right.

(c) Leading innovation ecosystems with strong international trade power such as the US exploits the regulatory discretion left by the TRIPS Agreement much more than other world leaders such as the EU, with positive rather than negative effects on the performance of companies relying on the US patent system. This gap gets even broader if one compares US policy responses with the tighter approach adopted by several developing countries, often upon the soft imposition of TRIPS-plus clauses contained in multilateral and bilateral investment treaties or free trade agreements (Grosse Ruse-Khan 2011).
Against this background, it becomes easier to understand why the Global South saw in a TRIPs waiver to fight the COVID-19 pandemic the only effective solution to come out from the standstill.

2. The request for a TRIPs waiver for COVID-19-related patents

As a response to the vaccine shortage, during the course of 2021 India, Sud Africa and more than 100 countries have asked a temporary TRIPs waiver to address the bottlenecks posed by the current international IP system to the world-wide fight against the COVID-19 pandemic. The waiver would have come on top of the suspension of TRIPs obligations for LDCs until 2034, last for three years with annual reviews, and allow Member States not to grant or enforce patents or other IPRs, including undisclosed information and trade secrets, related to Covid-19 products and technologies.
A revised version, tabled in May 2021, has limited the scope to health products and technologies (i.e. diagnostics, therapeutics, vaccines, medical devices and personal protective equipment) to tackle Covid-19. Such a request has been supported by more than 200 former government leaders and Nobel laureates, who have written an open letter to Mr. Biden. At last, the US decided to back the request, and President Biden became one of the loudest voices in support of the waiver. On the contrary, the European Union declared to be in favour of the extension of LDC's transitional period by another ten years, but the Commission issued a communication to the WTO opposing the waiver, and tabled an alternative proposal that focused on compulsory licensing, limiting export restrictions and expanding productions, but preserving patent rights. The Council supported this view in June 2021,[11] while the Parliament adopted three resolutions, all directed to support the need for a TRIPs waiver to tackle inequalities in access to vaccines. [12]

[11] Council Conclusions on Intellectual Property Policy, 18 June 2021, available at https://www.consilium.europa.eu/media/50529/st-9932-2021-init.pdf

[12] European Parliament resolution of 10 June 2021 on meeting the global COVID-19 challenge: effects of the waiver of the WTO TRIPS Agreement on COVID-19 vaccines, treatment, equipment and increasing production and manufacturing capacity in developing countries (2021/2692(RSP)), available at https://www.europarl.europa.eu/doceo/document/TA-9-2021-

This divergence among EU institutions, and among the EU and the US stands as yet another evidence of the recurrent blind faith in "the magic of the markets", often grounded on arguments that are contradictory and weakly evidence based. This is also the case for the arguments against the TRIPS waiver, whose fallacy has been pointed out by Stiglitz and Wallach, 2021 and Mazzucato et al., 2021 among others.

3. Dispelling false myths

Two reasons have been commonly advanced to oppose the adoption of a TRIPs waiver, *id est* (a) the waiver is useless as Global South Countries do not have the knowledge and the capability to produce vaccines, and (b) that it would stifle the future innovation of Big Pharma companies and thus leave us without responses against future pandemic threats. Now that at least a compromise text on a reduced TRIPs waiver has been adopted, the debate on the matter is slowly winding down. Yet, it is still worth confuting such arguments, not only to better inform the policy discussion on further instruments and solutions that have yet to be adopted, but also to evidence, once again, that more incisive interventions on the TRIPs system are still needed and represent the only viable option to allow a tech-transfer towards the Global South and to solve the current delay in the vaccination campaign in developing countries.

(a) The waiver is useless due to the knowledge gap in the Global South: false.

There are more than 250 firms worldwide which can produce vaccines, life-saving drugs and medical devices; there are at least 10 firms in the Global South which can manufacture mRNA vaccines, and the list of potential candidates is likely to be above 100. This strikingly contrasts with the fact that no pharmaceutical company has used the Covid-19 Technology Access Pool created by the WHO to transfer knowledge to Global South countries. Even though the mRNA is complex, less than seven months (from two to four months according to Suhaib Siddiqi, former director of chemistry at Moderna) would be required to transfer the necessary know-how and start the production of vaccines. The gap in technological transfer is so dramatic that WHO is supporting a South African company trying to reverse engineering techniques to replicate Moderna vaccine. Against this background, what proves to be useless are compulsory licenses as allowed under the current TRIPs regime. As illustrated above, the technological complexity of mRNA vaccines, the extent of technological knowledge covered by know-how and trade secrets and the international fragmentation of their supply chain makes such a balancing

0283_EN.html; European Parliament resolution of 7 July 2021 on the trade-related aspects and implications of COVID-19 (2020/2117(INI)), available at https://www.europarl.europa.eu/doceo/document/TA-9-2021-0328_EN.html; European Parliament resolution of 20 May 2021 on accelerating progress and tackling inequalities towards ending AIDS as a public health threat by 2030 (2021/2604(RSP)), available at https://www.europarl.europa.eu/doceo/document/TA-9-2021-0250_EN.html.

tool useless for the purpose of triggering a process of tech-transfer towards the Global South and boosting their local production of vaccines. On the contrary, a TRIPs waiver would make it impossible for pharmaceutical companies to enforce their patents until the end of the pandemic, thus allowing Global South firms to boost the reverse engineering of mRNA vaccines without the threat of being sued. Differently than the weak compulsory license instrument, this would reinforce the bargaining power of the Global South and act as a strong leverage for owners of patents over COVID-19 vaccines to cooperate in the technology transfer process, by securing agreements with Global South firms before suffering the drawbacks of uncensored patent infringements.

b) The waiver would stifle Big Pharma's future innovation, thus leaving us without responses against future pandemic/health threats: false.

The TRIPS waiver cannot reduce the innovation rate in the pharmaceutical sector, and particularly NOT in the field of vaccines. As we have already mentioned, the research is almost entirely supported by the public sector: for instance, at least 97% of the funding required for the development of the Oxford/AstraZeneca vaccine came from the government or charitable trusts (Cross et al., 2021). At the same times, vaccine sales are boosting the profits of company such as Moderna and Pfizer[13] thanks to the monopoly rents granted by patents. In fact, the TRIPS waiver will deprive Big Pharma only of the monopoly "super profits", while still receiving royalties and other forms of compensation for their vaccine-related property rights. Pharmaceutical companies could then keep on developing new vaccines, e.g. against the Omicron variant, relying on public funds and support and earning normal profits of the doses they manufacture.

4. From today's emergency responses to tomorrow's structural reforms for a fairer IP regime: policy recommendations for the EU and the WTO

Intellectual property rights have not been designed for emergencies such as wars and pandemics. In addition, the international standardization of intellectual property rights under the umbrella of the WTO has imposed a one-size-fits-all regime and straightjacketed the capability of national and regional governments to promptly adapt their IP laws to new challenges and needs. And while it is true that in the past the flexibilities provided by the TRIPs Agreement – particularly after the intervention of the Doha

[13] Conservative estimates suggest that the profit rate on COVID-19 jabs is higher than 20%. See https://investors.pfizer.com/investor-news/press-release-details/2021/PFIZER-REPORTS-FOURTH-QUARTER-AND-FULL-YEAR-2020-RESULTS-AND-RELEASES-5-YEAR-PIPELINE-METRICS/default.aspx.

Declaration on TRIPs and public health[14] – were enough to allow tackling other health emergencies such as the HIV epidemy,[15] compulsory licenses have proven to be of little use to respond to the policy challenges raised by the COVID-19 pandemic. Not only have they not contributed to close the gaps between the Global North and South as to the supply of vaccines and thus vaccination rate, but they did not foster either a real technology transfer process towards the Global South, which could have constituted a structural solution to the problem instead of a temporary patch - as it was the case for the COVAX program, which is not working well.

a. Today's emergency response: an ad hoc TRIPs waiver (and why the approved compromise text is not enough)

One and a half year down the road of COVID-19 vaccination campaigns, it is clear that compulsory licenses have failed to respond to the challenges and needs raised by the pandemic, in stark contrast with the role that compulsory licenses played during past health emergencies.

As a matter of fact, several countries that could have issued compulsory licenses to pressure vaccine producers decided to avoid it, opting instead for a massive financial intervention in the developmental phase and/or for early-stage negotiations to secure priority in supply and agree on specific contractual conditions. As a consequence, contractual leverages were used in critical moments (e.g. delays in delivery, reduced quantities delivered etc.), and the compulsory license option was never taken into account. This holds particularly true even for the EU, where this instrument was never really available. The Union, in fact, acted as a single entity *vis-à-vis* producers to have a stronger bargaining power, while the competence to issue compulsory licenses (and, in general, patent policies) lies on Member States, which abstained from intervening individually on the matter not to split the block. At the same time, a handful of countries (Israel, Hungary) have issued a compulsory license on Remdesivir, which ended in no result after the drug was later found to be ineffective against COVID-19 by WHO.

Against this background, it has long been clear that the only way out to overcome compulsory-license-related limitations and pitfalls was a temporary waiver from TRIPs obligations to tackle the COVID-19 emergencies. Only a waiver, in fact, could shield Member States from being sued before the Dispute Settlement Body of the WTO for non-compliance with the obligations arising from the TRIPs, thus giving them more room for manoeuvre against the constraints imposed by the international intellectual property regime.

[14] The Doha Declaration on the TRIPs Agreement and Public Health has clarified that WTO Member States have the right to use compulsory licenses under Article 31 TRIPs to safeguard health and, in this sense, they are free to determine what constitutes ground for it.

[15] Compulsory licenses have been widely used as a public health safeguards for, e.g., cancer treatments, direct-acting antivirals to treat hepatitis C ('t Hoen 2016).

At least theoretically, the original waiver proposal tabled by India and South Africa presented several advantages. *Inter alia*: (1) it would have helped overstep the limitations imposed to compulsory licensing under Article 31 TRIPs; (2) it would have freed the parallel import of generic products towards countries with reduced or no manufacturing capabilities from the complex bureaucratic requirements imposed by Article 31bis TRIPs, which have made the flexibility introduced by the provision literally useless and, in fact, rarely used since its entry into force; (3) it would have created more legal certainty and thus freedom to operate for alternative producers and suppliers of COVID-19-related medical products and services; (4) it would have helped public authorities from the Global South with limited IP skills adopt more courageous actions without the fear of being subject to commercial sanctions; (5) it would have created a strong leverage to stimulate technology transfer from the Global North to the Global South, encouraging cooperation between original vaccine producers and generic companies; (6) last, it would have laid down the policy preconditions and evidence for a more structural revision of the TRIPs system, in order to make it more efficient and fit for future emergencies.

More generally, the waiver carried with it the promise to reduce the monopoly power of pharmaceutical companies, nudging them to cooperate with Global South firms in order to effectively transfer the knowledge required to manufacture vaccines and other life-saving drugs and medical devices in exchange of fair compensation.

This potential was largely underestimated and downplayed in the policy debate. Countervailing arguments and fears prevailed, and this resulted in the adoption of a compromise text on a TRIPs waiver which, although it represents a step forward, it is presents severe limitations and flaws.

The approved "Draft Ministerial Decision on the TRIPs Agreement" shows limitations as to the subject-matter of the waiver, for it focuses only on patents and carves out other IP rights and trade secrets which, as highlighted above, may cover elements that are fundamental for manufacturing. In a similarly problematic fashion, it limits eligible members to a category that is yet to be defined (indicated as "pending" in the related footnote)., and it links the production and supply of COVID-19 pandemics without the consent of rightholders "in accordance with the provisions of Article 31 of the Agreement", that is the provision on compulsory licenses. And while it is true that several cumbersome requirements imposed by Article 31 TRIPs are suspended, such as the need to make efforts to negotiate with rightholders, or to limit the production to domestic supply only – thus allowing free export to countries with reduced manufacturing capabilities – the waiver still maintains the need for an equitable remuneration to be paid. Compared to the previous compromise proposal, the approved text eliminated the requirement for governments to issues authorizations on a product-by-product basis, and to identify all patents covered by the authorization before enjoying the waiver, thus avoiding the imposition of complex and cumbersome conditions which could hinder the capability of not too "skilled" governments to enjoy the benefits of the waiver. Yet, eligible Members should still "undertake all reasonable efforts

to prevent the re-exportation of the product manufactured under the authorization (…) that have been imported into their territories under this Decision", and "shall ensure the availability of effective legal means to prevent the importation into, and sale in, their territories, of products manufactured under the authorization (…) and diverted to their markets inconsistently with its provision" – a circumstance that brings back to the table the risk of controversies and litigation before the DSB.

Last, the waiver is limited to vaccine. Although it leaves the possibility to include treatments and diagnostic within six months from the date of this decision this exclusion still severely weaken the potential the waiver has to increase access to COVID-19 medical tools for low and middle-income countries, in a historical moment where ex post therapies are as important to decrease deaths and permanent consequences of COVID as preventive vaccines are.

b. Beyond the COVID-19 waiver: the need for structural reforms of the TRIPs regime

This pandemic will not be the last one given the environmental destruction that characterize the Anthropocene (Coriat, 2020; Crutzen, 2006). The unpreparedness of developed countries to swiftly tackle the pandemic stems from the deeply dysfunctional relationship between the private and the public in the generation and exploitation of innovative knowledge. Such a dysfunctionality rests upon the negative evolution of IPRs over the last forty years (see. e.g. the Bayh-Dole Act in the USA in 1980), expanding the domain of patentability to the knowledge generated with public resources and the width and span of patents themselves. The effects are particularly bad in the generation of health-related knowledge as the public sector continues to support fundamental research, while Big Pharma masters the rates and directions of innovative activities and pile up profits selling back drugs mostly financed with public money.

The evidence generated during the COVID-19 emergency, coupled with data and phenomena observed along the road of 25 years of TRIPs regime, are enough to perform a well-grounded impact assessment of the WTO international IP system, and to draw conclusions on the real effects of its one-size-fits-all standardization. They all point to the need for structural reforms of the TRIPs Agreement, directed to tackle its most evident pitfalls.

Indeed, the current setup of IPRs is designed to maximize the rent of patent holders instead of the innovation output, thus hampering science and the economies of both developed and developing countries (Dosi and Stiglitz, 2014). The evidence is particularly striking in the pharmaceutical industry, where before TRIPS, generics obtained under loose IPR regimes were able to dramatically reduce the cost of drugs available to developing countries (and would continue to be so outside TRIPS: recall the

case of generic antiretroviral drugs against the HIV virus which reduced the cost by between 98% and 70%, cf. Coriat et al., 2006; and So et al., 2014).

1. The very first principle to be reformed is the mandatory extension of the patentable subject matter to all fields of technologies, without discrimination, and with very limited exemptions (art.27 TRIPs). The current negative effects of the one-size-fit-all approach to the matter suggest the need either (a) to remit the determination of specific exclusions to Member States, subject to adequate justification before the WTO TRIPs Council or (b) to broaden the list of inventions and/or industries that might be excluded from patentability in specific circumstances, based on economic evidence.
2. The second area requiring intervention is that of flexibilities and derogations. While it is true that the Doha Declaration on TRIPs and Public Health empowered the tool of compulsory licenses under Article 31 TRIPs, the introduction of Article 31bis TRIPs answered to the need of developing countries with low or no manufacturing capabilities, and least developed countries are exempted from TRIPs-related obligations still until 2034, the COVID-19 pandemic showed that such balancing rules may still be insufficient in specific circumstances. Again, two solutions are possible. One, more conservative, would be to include in the TRIPs additional flexibility rules to improve the system, such as, *inter alia,* (much) less bureaucratic processes to enact the mechanism of Article 31bis, broader coverage for compulsory licenses (both in terms of subject-matter and in terms of patents covered, particularly when the invention is subject to patent thickets), mandatory discovery rules for patent holders/developers (e.g. on know-how et al.). The second, more "revolutionary", would be to offer more leeway to Member States to determine IP flexibilities.
3. This second option, in fact, would largely overlap with the third matter requiring intervention, which is that of TRIPs waivers. The long and bumpy road that has characterized the current TRIPs waiver proposal clearly shows the impossibility to rely on diplomatic discussions and agreements before the TRIPs Council to tackle emergency situations such as those triggered by the current pandemic. To avoid vetoes or other dragging techniques, it would be advisable to introduce within the TRIPs Agreement a norm determining specific cases where TRIPs waivers could be activated automatically, upon the decision of an independent body, or with basic majorities, and in any case without the necessity of a consensus.
4. Last, commercial sanctions should be redefined or completely excluded in case of TRIPs violations that are justified and backed by external motions (e.g. from the WTO, UN, WIPO, FAO etc). This would need to cover not only sanctions issued by the WTO Dispute Settlement Body, but also sanctions imposed by Member States within their own competence and discretion,

which would need to be banned in order to avoid their strong chilling effects on economically weaker or dependent countries.

Aside from general structural reforms, specific interventions are needed to clarify the feasibility, within the current TRIPs system, of certain policy options which by now have been implemented only by strong players such as the US, which has less to fear vis-à-vis other Member States. Such a clarification would not only pave the way for similar attempts by Global South countries, once freed from potential commercial threats, but would also shed light on the room of manoeuvre available for other economic super-powers like the EU, which would then be called to justify the reasons underlying the adoption of different policy options. A major example is the treatment of inventions developed mostly by public money and public research. In such cases, as patents are a major mechanism of rent appropriation, the public sector should get the control of the whole innovation process from the research all the way to experimentation on humans (i.e. from Phase I to III), and when successful, transfer to Big Pharma, on nonexclusive base, the license to produce – which at that point should yield costs and thus prices not be too different from marginal costs. This would allow the public sector to regain the control over the rates and directions of innovative activities and to save public funds which can be invested in health and other expenditures. Finally, it would boost the access of Global South countries to lifesaving drugs.

c. How can the EU do its part?

Patents represent one of the least harmonized areas of EU intellectual property law. In this respect, the EU innovation and policy ecosystem is characterized by a patchwork of national solutions, since patent laws remain very much country-based, and this is likely to remain so also after the entry into force of the Unitary Patent system (Ullrich 2012). However, this does not mean that the EU does not have any policy and regulatory role to still undertake in the field. Article 118 TFEU gives to the Union the competence to introduce a real unitary patent on the basis of a comprehensive regulation, as is the case for the EU trademark, and Article 114 TFEU allows interventions on national patent laws every time this is requested to ensure the proper functioning of the internal market. Internal market needs, in fact, may suffice to support an EU harmonizing intervention on several matters, and particularly on those where diverging national solutions would trigger the risk of negative competition between national legal systems and a race-to-the-bottom to attract foreign investments.

Against this background, the evidence accrued in the past two years have highlighted the shortcomings of the EU regulatory ecosystem vis-à-vis the emergencies and needs triggered by the pandemic, particularly if compared to the resilience and efficiency of the US response. This strongly suggests the needs to intervene along the following lines, within the regulatory framework of **the Unitary Patent Package.**

1. **Harmonizing the treatment of publicly funded inventions**, using the US model as examples of efficient balance between private incentives and protection of the public interest and public investments. Mechanisms of price control, minimum output rules, reverse licensing, and compulsory licenses in case of breach of regulatory requirements are some of the key provisions which should be evaluated through an impact assessment within the EU context to confirm their suitability to the EU and national industrial ecosystem.
2. **Harmonizing the regulation of compulsory licenses and providing a uniform system of exceptions across the Union**, not only to remove obstacles for the proper functioning of the internal market, but also to align the EU legal system to the same common-position approach that has recently characterized the reaction of the EU vis-à-vis the pandemics, particularly when negotiating deals with pharmaceutical companies.
3. For similar reasons, **introducing a system of EU-wide compulsory licenses**, attributing the competence to issue EU-wide licenses to a **specialized body within EPO or the EUIPO.**

5. Taking stocks and looking ahead

A change of the current IPR regimes, and thus a reform of the TRIPs Agreement is urgently needed to restore the universal public good character of health and boost innovation in the pharmaceutical sector. The European Union should have a pivotal role is supporting such reforms. However, a change of the IPR regimes is not sufficient. *Innovation and industrial policies* are needed to support an active role of the government in the economy. In the short-run, this would speed the international technological transfer required to produce COVID-19 vaccines in Global South Countries. In the medium, and long-run it can spur technological progress and growth *in both* the "South" and in the Advanced North. A good example is the Arsenal of Democracy created by the U.S.A during the WWII which has led to the development of the new antibiotic industry (see Gross and Sampat, 2020, 2021, 2022 and Best and Bradley, 2020). Such forms of public intervention have permanently changed U.S. innovation policy and also explains the success of Operation Warp Speed (Adler, 2021). Similarly, the success of Cuban policies (Reardon, 2021) against the pandemic rest on the development of the first COVID-19 sub-unit vaccine in the world by the public biotech industry. Note that these are *non-market* interventions performed by what Mazzucato, (2013) calls an *Entrepreneurial State*. We are at war with the COVID-19 pandemic and we need a global Operation Warp Speed (Bown and Bollyky, 2021) to boost now the technological transfer under the COVID-19 patent waiver, but more generally to the global preparedness for future pandemics. For sure this will not be the last one.

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